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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/773,604 | 02/05/2004 | Thomas Roballey | 1330.004 | 7751 |
| 27353 | 7590 | 12/29/2004 | EXAMINER | |
| MELVIN K. SILVERMAN 500 WEST CYPRESS CREEK ROAD SUITE 500 FT. LAUDERDALE, FL 33309 | | | SNOW, BRUCE EDWARD | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,604

Applicant(s)

ROBALLEY, THOMAS

Examiner

Bruce E Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the preamble is not commensurate with that of claim 9 from which it depends.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 16, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerow et al (4,795,463).

Gerow teaches a method of detecting rupture of a prosthesis comprising:

(a) implanting a prosthesis containing a fill (chemical indicator), Gerow teaches, *"radiopaque marker which absorbs electromagnetic energy different from the envelop and its contents (chemical indicator) and different from the surrounding breast tissue and in a pattern or configuration which enable roentgenographic determination of whether the envelope is intact, has ruptured."*

(b) detecting a change locally around the prosthesis using x-ray for indication of leaking out of said indicator from said prosthesis. Note

Regarding claim 11, using x-ray inherently detects a change in the "peripheral blood" surrounding the implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (4,969,899) in view of Gerow (4,795,463).

Cox teaches a prosthesis comprising:

(a) an external envelope 41 of medical grade elastomer containing a silicone gel fluid material 40 and

(b) an internal envelope 11 of medical grade elastomer disposed within said external envelope, said internal envelope containing an implant filling material.

However, Cox is silent regarding a chemical indicator for indicating rupture within the external envelope.

Gerow teaches using radiopaque materials on the envelopes and further teaches it is possible to use a radiopaque material in the silicone gel fill material. See column 5, lines 3-10. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Gerow and used a radiopaque material in the silicone gel fill material to better differentiate from the body or used in combination with radiopaque material on the envelope to check for ruptures of the envelope.

Regarding claim 8, the references teach at least a breast prosthesis which is a genital prosthesis.

Regarding the use of a dye, odour generating, sensation agent, etc., the combination rejection teaches using x-ray to check for ruptures, applicant's specification teaches this also from a list including skin color change, local sensation, etc.; see at least page 8, lines 9 et seq. and claim 19. Lacking any criticality in the specification the use of the a dye, odour generating, sensation agent, etc. in lieu of that taught by the references produces no advantages and is considered an obvious matter of design choice to one skilled in the art. This includes claims 12-15 and 17-18.

Regarding claim 11, using x-ray as used in the combination rejection inherently detects a change in the "peripheral blood" surrounding the implant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'BSN', with a stylized flourish extending from the end.

BRUCE SNOW
PRIMARY EXAMINER